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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,818	06/26/2003	Thomas Nilsson	239637US0	2767

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/28/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/603,818	NILSSON ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the IDS filed on 10/16/06 and the Amendments and Remarks filed on 11/08/06. Claims 18-38 have been cancelled and new claims 39-60 have been added. Accordingly claims 39-60 are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (WO 03061743).

Anderson et al disclose a medicament dispenser for use with plural elongate form medicament carriers, each having multiple distinct medicament dose portions carried thereby (see abstract). The medicament carrier comprises a blister pack in laminate form. The laminate comprises material selected from the group consisting of metal foil, organic polymeric material and paper (page 3, lines 27-30). A blister pack may comprise a peelable blister strip. The peelable blister strip comprises a base sheet in which blisters are formed to define pockets therein for containing distinct medicament dose portions and a lid sheet which is hemetically sealed to the base sheet (see page 4, lines 4-14). It is also disclosed that each dose portion comprises a single active (i.e. mono-active) medicament component. Each mono-active component is therefore brought together **only at the time of release** to form the overall combination product (page 5, lines 14-16).

Anderson et al discloses that one preferred configuration is the "side-by-side" configuration, in which for example, two carriers (e.g. two coiled blister strips) are arranged to lie in sideways alignment with each other in the dispenser (page 7, lines 8-10). A mechanism of release for releasing a distinct medicament dose portion from each of the plural medicament carriers on its receipt by the receiving station is employed. The release can have any suitable form. Where the elongate carrier is in the form of a blister strip, the release may for example, comprise means to rupture, puncture, tear or otherwise access the blister (see page 9, lines 9-17).

Anderson discloses that the said medicament dispenser is suitable for dispensing medicament combinations, particularly for the treatment of respiratory disorders such as

asthma and chronic obstructive pulmonary disease, bronchitis, etc (see page 69, lines 6-8). Appropriate medicaments may thus be selected from anti-inflammatories, bronchodilators, antiallergics, etc. The suitable active agents include budesonide, fluticasone, mometasone, ciclesonide, formoterol, tiotropium, etc, and their salts, solvates. Preferred components for combination medicaments include fluticasone, salmeterol, beclomethasone, etc and salts and solvates thereof (page 70, lines 10-26).

Particles of the powdered medicament and/or excipient may be produced by conventional techniques, for example by micronization, milling or sieving (page 71, lines 8-13). A standard blend may contain 13000 microgram of lactose and 50 micrograms of drug (page 71, lines 15-21).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bralthwaite et al (EP 1300171 A2) in view of Gavin (WO 0178737).

Bralthwaite et al teach a delivery device which comprises a reservoir, a delivery passage for the delivery of material and metering member. Also a method of administering a dry powder to a patient with a bronchial disorder is disclosed (see abstract). The metering member is adapted to transfer one or more measured doses of medicament from one or more of the medicament reservoirs to the delivery passage.

Therefore the metering member is preferably provided with dual measuring chambers or a series of dual measuring chambers (see [0012]).

Bralthwaite et al also discloses that in a combination therapy inhaler, there are two medicament pockets provided. In operation, the device may be moved to a first position in which the first medicament is transferred to a first chamber in the metering member. The device is then moved to a second position in which a second medicament is transferred from a second measuring chamber. Then either separately or together the metering members are rotated to a third position where medicament is delivered to the delivery passage (see [0018]).

Bralthwaite et al teach that a variety of medicaments may be administered by using the said inhaler. Such medicaments include anti-inflammatories, bronchodilators, antibiotics and other respiratory drugs. Said drugs include formoterol, salmeterol, fluticasone, budesonide, etc, or a combination thereof (see [0021] and [0022]).

Bralthwaite et al lacks disclosure on the amount of medicaments and some of the active agents.

Gavin teaches medical combinations comprising **formoterol and budesonide**. The combinations are used for prophylaxis and treatment of respiratory diseases (see abstract). The active agents may be a racemate, solvate, hydrate or functional derivative thereof. The formulations may comprise other active agents such as **fluticasone propionate**, beclomethasone dipropionate, **mometasone furoate** or triamcinolone acetonide, salbutamol, salmeterol, tiotropium, etc (see pages 5-6). The

formulations may be in a form for inhalation such as **fine particle** dust administered via **metered dose aerosols**. Formulations for inhalation include **powder** compositions which will preferably contain lactose. The active ingredients will have a particle size of less than 100 microns, and preferably from 1 to 5 microns (see page 6).

The amounts of each active agent is disclosed in various examples, such as example 3, where **a** dry powder formulation comprises 24 microgram of (R,R)-formoterol fumarate and 200 microgram of budesonide. The process of making the said formulations are disclosed in page 9 which reads "the active ingredients are micronised and bulk blended with lactose and filled into hard gelatin capsules or cartridges or in specifically constructed **double foil blister packs** to be administered by an inhaler such as a Rotahaler®, Disckhaler® or Disckus® inhaler".

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the device and method of Bralthwaite et al on making and delivering particle formulations comprising two or more active agents with the formulations comprising two or more active agents as taught by Gavin because of the said advantages of delivering powdered combination medicaments where by storing the active agents separately, the problems of aggregation and degradation is resolved. Furthermore, it would have been obvious to one of ordinary skill in the art, given the general teachings of Bralthwaite et al to have looked in the art for other active agents, suitable for treating respiratory disorders used in the combination therapies and for their suitable amounts in the said combinations.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Trofast (6,030,604) teaches a dry powder composition comprising one or more potent pharmaceutically active substances and a carrier substance, all of which are in finely divided form. The active substance suitable for use in the invention include **ciclesonide,** formoterol, budesonide, mometasone, fluticasone, salmeterol, etc (see col. 1, lines 26-62). The particle size of the active ingredients is said to be less than 10 microns and preferably between 1 and 7 microns. The formulations comprises about 6 microgram of formoterol and 100 microgram of budesonide per unit dose (see col. 2, lines 3-10 and 15-49). The said formulations can be administered via dry powder metered dose inhalers, to patients suffering form disorders such as respiratory disorders (col. 3, lines 20-31).

Response to Arguments

Applicant's arguments with respect to claims 18-38 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
January 22, 2007

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